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B3 26. A food according to claim 24 wherein said cytotoxic agent includes at least one of estramustine phosphate, prednimustine, cisplatin, 5-fluoro-uracil, melphalan, hydroxyurea, mitomycin, idarubicin, methotrexate, adriamycin, daunomycin, cyclophosphamide, doxorubicin, vincristine and pregnisone.

B4 31. A food according to claim 30 wherein said pharmaceutically acceptable organic and pharmaceutically acceptable inorganic carrier substances include at least one of water, salt solutions, alcohols, gum arabic, mineral and vegetable oils, benzyl alcohols, polyethylene glycols, gelatine, carbohydrates such as lactose, amylose or starch, magnesium stearate, talc, silicic acid, viscous paraffin, perfume oil, fatty acid monoglycerides and diglycerides, pentaerythritol fatty acid esters, hydroxy methylcellulose, and polyvinyl pyrrolidone.

PLEASE ADD THE FOLLOWING NEW CLAIM

B5 34. A pet food for feeding to a pet, said pet food comprising at least one vitamin D analog and at least one of a bone agent, a cytotoxic agent and an anti-inflammatory agent.

REMARKS

Claims 13-34 are now pending in the application. Claims 13-33 stand rejected. Claims 1- 12 have been cancelled. Claim 34 is newly added.

A fee calculation sheet for the newly added claim along with authorization to charge a deposit account in the amount of the calculated fee are submitted herewith.

Submitted herewith are marked up Specification and Claims in accordance with 37 C.F.R. 1.121(c)(1)(ii).

The objection to Claims 14, 16-17, and 25-26 due to informalities is respectfully traversed. The Office Action indicated that the employment of parenthetical expressions "(analog V)", "(EB 1089)", "(DHEA)", "(hydroxydaunorubicin)", "(oncovin)" and "(buffer)" was considered to be informal and correction was requested. Claims 14, 16-17, 25-26 and 31 have been amended to correct the indicated informalities. No new matter is presented by this amendment. OK

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The rejection of Claims 13-16, 18, 23 and 30-32 under 35 U.S.C. § 102(b) as being anticipated by Baggiolini et al (5,087,619) is respectfully traversed. Baggiolini et al. teach a method of treating leukemia and basal cell carcinoma in a warm-blooded animal comprising administering an effective amount of a vitamin D analog. The analog is provided to the animal either orally or topically. The oral administrations include capsules and tablets.

Claim 13 recites a food for dogs comprising a vitamin D analog. Baggiolini et al do not describe nor suggest a food for dogs comprising a vitamin D analog. Rather, Baggiolini et al describe providing a vitamin D analog to an animal either topically or orally (via ingestion of capsules or tablets.) Capsules and tablets are not food for dogs. For the reasons set forth above, Claim 13 is submitted to be patentable over Baggiolini et al.

Food
v.
pill

Claims 14-16, 18, 23, and 30-32 depend, directly or indirectly, from independent Claim 13. When the recitations of Claims 14-16, 18, 23, and 30-32 are considered in combination with the recitations of Claim 13, Applicant submits that dependent Claims 14-16, 18, 23, and 30-32 likewise are patentable over Baggiolini et al.

For the reasons set forth above, Claims 13-16, 18, 23, and 30-32 are submitted to be patentable over Baggiolini et al.

The rejection of Claims 13-23 and 30-32 under 35 U.S.C. § 103(a) as being unpatentable over Baggiolini et al. and Yu et al. (PMID 7756673) is respectfully traversed.

Baggiolini et al is described above. Yu et al. describe experiments conducted with respect to a human cell line and reports examinations of in vitro effects of 1,25 dihydroxy-vitamin D₃ 1,25 (OH)₂D₃ and of two side chain analogs of 1,25(OH)₂D₃ (EB1089 and MC903) on cell growth and parathyroid hormone related peptide (PTHrP) production in immortalized (HPK1A) and neoplastic (HPK1A-ras) keratinocytes.

Claim 13 recites a food for dogs comprising a vitamin D analog. Applicant respectively submits that Baggiolini et al and Yu et al., alone or in combination neither teach nor suggest a food as recited in Claim 13. Baggiolini et al describe providing a vitamin D analog to an animal either topically or orally (via ingestion of capsules or tablets) and does not describe a food for dogs. Yu et al describe observing the effects of vitamin D analogs in immortalized and neoplastic keratinocytes. Neither Baggiolini et al nor Yu et al describe a

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food as recited in Claim 13. For the reasons set forth above, Applicant respectfully requests that the Section 103 rejection of Claim 13 be withdrawn.

Claims 14-23 and 30-32 depend, directly or indirectly, from independent Claim 13. When the recitations of Claims 14-23 and 30-32 are considered in combination with the recitations of Claim 13, Applicant respectfully submits that dependent Claims 14-23 and 30-32 likewise are patentable over Baggiolini et al and Yu et al.

Notwithstanding the above, the rejection of Claims 13-23 and 30-32 under 35 U.S.C. § 103(a) as being unpatentable over Baggiolini et al and Yu et al is further traversed on the grounds that the Section 103 rejection of the presently pending claims is not a proper rejection. Obviousness cannot be established by merely suggesting that it would have been obvious to one of ordinary skill in the art to modify Baggiolini et al using the teachings of Yu et al. More specifically, as is well established, obviousness cannot be established by combining the teachings of the cited art to produce the claimed invention, absent some teaching, suggestion, or incentive supporting the combination. It is impermissible to use the claimed invention as an instruction manual or "template" to piece together the teachings of the prior art so that the claimed invention is rendered obvious. Specifically, one cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention. Further, it is impermissible to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art.

As the Federal Circuit has recognized, obviousness is not established merely by combining references having different individual elements of pending claims. Ex parte Levengood, 28 U.S.P.Q.2d 1300 (Bd. Pat. App. & Inter. 1993). MPEP 2143.01. Rather, there must be some suggestion, outside of Applicants' disclosure, in the prior art to combine such references, and a reasonable expectation of success must be both found in the prior art, and not based on Applicants' disclosure. In re Vaeck, 20 U.S.P.Q.2d 1436 (Fed. Cir. 1991). In the present case, neither a suggestion or motivation to combine the prior art disclosures, nor any reasonable expectation of success has been shown.

Neither Baggiolini et al nor Yu et al, considered alone or in combination, describe nor suggest the food recited in Claim 13. Baggiolini et al describe providing a vitamin D analog to an animal either topically or orally (via ingestion of capsules or tablets) and does not

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describe a food for dogs. Yu et al. pertains to a human cell line and specifically reports that they have examined the in vitro effects of 1,25 dihydroxy-vitamin D₃ [1,25 (OH)₂D₃] and of two side chain analogs of 1,25 (OH)₂D₃ (EB1089 and MC903)) on cell growth and PTHRD production in immortalized (HPK1A) and neoplastic (HPK1A-ras) human keratinocytes. Neither Baggiolini et al nor Yu et al describe or suggest a food for dogs comprising a vitamin D analog. Rather, the present Section 103 rejection appears to be based on a combination of teachings selected from multiple patents in an attempt to arrive at the claimed invention. Specifically, Baggiolini et al is cited for teaching vitamin D analogs in oral dosage forms such as capsules or tablets and Yu et al is cited for teaching that EB 1089 is known to inhibit cell proliferation and may be useful against neoplastic diseases in human. Since there is no teaching nor suggestion for the combination of Baggiolini et al and Yu et al, the Section 103 rejection appears to be based on a hindsight reconstruction in which isolated disclosures have been picked and chosen in an attempt to deprecate the present invention. Of course, such a combination is impermissible, and for this reason alone, Applicant requests that the Section 103 rejection of Claims 13-23 and 30-32 be withdrawn.

For at least the reasons set forth above, Applicant respectfully requests that the 35 U.S.C. § 103(a) rejection of Claims 13-23 and 30-32 be withdrawn.

The rejection of Claims 24-29 and 33 under 35 U.S.C. § 103(a) as being unpatentable over Baggiolini et al. and Yu et al. in view of Katzung and Hardman et al is respectfully traversed.

Baggiolini et al. and Yu et al are described above.

Katzung describes that hypercalcemia may cause central nervous system depression, including coma and is potentially lethal. Its potential causes (other than thiazide therapy) are hyperparathyroidism and cancer with or without bone metastases. Further Katzung explains that less probable causes are hypervitaminosis D, sarcoidosis, thyrotoxicosis, mil-alkali syndrome, adrenal insufficiency and immobilizations. Katzung does not describe nor suggest pets, dogs, or food for dogs.

Hardman et al describes the use of opioids to treat patients with malignant disease or terminal illness. Hardman does not teach nor suggest that pain is commonly associated with cancer. Hardman appears to be non-analogous art since Hardman does not describe nor suggest pets, dogs, or food for dogs.

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Claim 24 depends from Claim 13 which recites a food for dogs comprising a vitamin D analog. Applicant respectfully submits that Baggiolini et al and Yu et al in view of Katzung and Hardman et al, alone or in combination do not teach or suggest a food as recited in Claim 13. Baggiolini et al describe providing a vitamin D analog to an animal either topically or orally (via ingestion of capsules or tablets) and does not describe a food for dogs. Yu et al describe observing the effects of vitamin D analogs in immortalized and neoplastic keratinocytes. Katzung describes that hypercalcemia may be caused by hypervitaminosis D. Hardman et al describe the use of opioids to treat patients with malignant disease or terminal illness. None of Baggiolini et al, Yu et al, Katzung, and Hardman et al, taken alone or together, teach or suggest a food as recited in Claim 13. For the reasons set forth above, Applicant respectfully requests that the Section 103 rejection of Claim 13 be withdrawn.

Claim 24 depends from Claim 13 and additionally recites that the food further comprises a bone agent, a cytotoxic agent, an immuno response regulating agent, and an anti-inflammatory agent. None of Baggiolini et al, Yu et al, Katzung, and Hardman et al, taken alone or together, teach or suggest a food as recited in Claim 13 and further comprising a bone agent, a cytotoxic agent, an immuno response regulating agent, and an anti-inflammatory agent. For the reasons set forth above, Applicant respectfully requests that the Section 103 rejection of Claim 24 be withdrawn.

Claims 25-29 depend, directly or indirectly, from Claim 24. When the recitations of Claims 25-29 are considered in combination with the recitations of Claim 24, Applicant respectfully submits that dependent Claims 25-29 likewise are patentable over Baggiolini et al and Yu et al in view of Katzung and Hardman et al.

Claim 33 recites a food for treating cancer in pets . . . comprising a vitamin D analog, a bone agent, a cytotoxic agent and a anti-inflammatory agent. None of Baggiolini et al, Yu et al, Katzung, and Hardman et al, taken alone or together, teach or suggest a food as recited in Claim 33. Baggiolini et al describe providing a vitamin D analog to an animal either topically or orally (via ingestion of capsules or tablets) and does not describe a food for dogs. Yu et al describe observed effects of Vitamin D analogs in immortalized and neoplastic keratinocytes. Katzung describes that hypercalcemia may be caused by hypervitaminosis D. Hardman et al describe the use of opioids to treat patients with malignant disease or terminal illness. None of Baggiolini et al, Yu et al, Katzung, and Hardman et al, taken alone or

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together, teach or suggest a food as recited in Claim 33. For the reasons set forth above, Applicant respectfully requests that the Section 103 rejection of Claim 33 be withdrawn.

Notwithstanding the above, the rejection of Claims 24-29 and 33 under 35 U.S.C. § 103(a) as being unpatentable over Baggiolini et al and Yu et al in view of Katzung and Hardman et al is further traversed on the grounds that the Section 103 rejection of the presently pending claims is not a proper rejection. Obviousness cannot be established by merely suggesting that it would have been obvious to one of ordinary skill in the art to modify Baggiolini et al and Yu et al by using the teachings of Katzung and Hardman et al. More specifically, as is well established, obviousness cannot be established by combining the teachings of the cited art to produce the claimed invention, absent some teaching, suggestion, or incentive supporting the combination. It is impermissible to use the claimed invention as an instruction manual or "template" to piece together the teachings of the prior art so that the claimed invention is rendered obvious. Specifically, one cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention. Further, it is impermissible to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art. In the present case, neither a suggestion or motivation to combine the prior art disclosures, nor any reasonable expectation of success has been shown.

None of Baggiolini et al, Yu et al, Katzung and Hardman et al considered alone or in combination, describe or suggest the food recited in Claims 24-29 and 33. Rather, the present Section 103 rejection appears to be based on a combination of teachings selected from multiple patents in an attempt to arrive at the claimed invention. Specifically, Baggiolini et al is cited for teaching vitamin D analogs in oral dosage forms such as capsules or tablets and Yu et al is cited for teaching that EB 1089 is known to inhibit cell proliferation and may be useful against neoplastic diseases in human. Katzung is cited for teaching that hypercalcemia is a consequence of hypervitaminosis D and Hardman et al is cited for teaching that pain is commonly associated with cancer. Since there is no teaching nor suggestion for the combination of Baggiolini et al, Yu et al, Katzung and Hardman et al, the Section 103 rejection appears to be based on a hindsight reconstruction in which isolated disclosures have been picked and chosen in an attempt to deprecate the present invention. Of course, such a combination is impermissible, and for this reason alone, Applicant requests that the Section 103 rejection of Claims 24-29 and 33 be withdrawn.

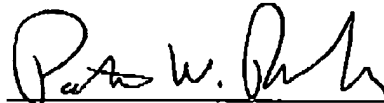
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For the reasons set forth above, Applicant respectfully requests that the 35 U.S.C. § 103(a) rejection of Claims 24-29 and 33 be withdrawn.

It is believed that all pending claims are in condition for allowance for at least the reasons set forth above. The recitations in the pending claims are not taught nor suggested in the art cited in the Office Action and thus all claims are deemed to be patentable. The patentability of each dependent claim on its own merits is respectfully requested since each dependent claim is also deemed to recite an additional aspect of the invention requiring consideration or reconsideration, as the case may be.

In view of the foregoing amendments and remarks, all claims now active in this application are believed to be in condition for allowance. Reconsideration is requested along with early passage to issue. Favorable action and allowance are respectfully solicited.

Respectfully submitted,



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Express Mail No.: E\ 0051065US**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: Nongnuch Inpanburr

Art Unit: 1617

Serial No.: 10/026,006

Examiner: Mojdeh Bahar

Filed: December 21, 2001

Atty Dkt. No.: No. 7331/US

For: **METHOD AND PRODUCT FOR
TREATING CANCER IN PETS****SUBMISSION OF MARKED UP SPECIFICATION AND CLAIMS UNDER 37
C.F.R. 1.121(c)(1)(ii).**Hon. Commissioner for Patents
Washington, D.C. 20231

Sir:

Submitted herewith are marked up Claims in accordance with 37 C.F.R.
1.121(c)(1)(ii) wherein additions are underlined and deletions are [bracketed].

14. (once amended) The food of claim 13, wherein the vitamin D analog is selected from the group consisting of $1\alpha,25-(\text{OH})_2\text{D}_3$, $1\alpha,25-(\text{OH})_2-16\text{-ene-}23\text{-yne- D}_3$ [(analog V)], and $1\alpha,25-(\text{OH})_2-22,24\text{-diene-}24,26,27\text{-trihomo-D}_3$ [(EB 1089)] and stereoisomers thereof.

16. (once amended) The food of claim 13, wherein the vitamin D analog is $1\alpha,25-(\text{OH})_2-16\text{-ene-}23\text{-yne- D}_3$ [(analog V)] and stereoisomers thereof.

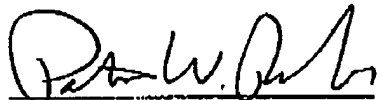
17. (once amended) The food of claim 13, wherein the vitamin D analog is $1\alpha,25-(\text{OH})_2-22,24\text{-diene-}24,26,27\text{-trihomo-D}_3$ [(EB 1089)] and stereoisomers thereof.

25. (once amended) A food according to claim 24 wherein said bone agent includes at least one of conjugated estrogens, conjugated estrogen equivalents, anti-estrogens, calcitonin, bisphosphonates, calcium supplements, calcium receptor agonists, cobalamin, pertussis toxin, boron, dehydroepiandrosterone [(DHEA)], activin and bone morphogenic protein.

26. (once amended) A food according to claim 24 wherein said cytotoxic agent includes at least one of estramustine phosphate, prednimustine, cisplatin, 5-fluoro-uracil, melphalan, hydroxyurea, mitomycin, idarubicin, methotrexate, adriamycin, daunomycin, cyclophosphamide, doxorubicin [(hydroxydaunorubicin)], vincristine [(oncovin)] and pregnisone.

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31. (once amended) A food according to claim 30 wherein said pharmaceutically acceptable organic and pharmaceutically acceptable inorganic carrier substances include at least one of water[,] and salt [(buffer)] solutions, alcohols, gum arabic, mineral and vegetable oils, benzyl alcohols, polyethylene glycols, gelatine, carbohydrates such as lactose, amylose or starch, magnesium stearate, talc, silicic acid, viscous paraffin, perfume oil, fatty acid monoglycerides and diglycerides, pentaerythritol fatty acid esters, hydroxy methylcellulose, and polyvinyl pyrrolidone.



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